

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLEXXIKON INC.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

Case No. [17-cv-04405-HSG](#)

**ORDER GRANTING IN PART AND
DENYING IN PART PLAINTIFF'S
MOTION IN LIMINE NO. 4 AND
DENYING PLAINTIFF'S MOTION IN
LIMINE NO. 5**

Re: Dkt. Nos. 264, 266

The Court rules on the pending motions in limine ("MIL") as detailed below.

I. PLAINTIFF'S MIL NO. 4

Plaintiff Plexxikon Inc. moves to preclude Defendant Novartis Pharmaceuticals Corporation from offering certain evidence at trial regarding: (1) Defendant's claim that it did not willfully infringe the asserted patents; (2) the development and commercialization of Mekinist, a drug that is prescribed and sold in combination with Tafenlar (the accused product); and (3) Defendant's due diligence in purchasing GSK's oncology portfolio (which included Tafenlar). *See* Dkt. No. 264. Plaintiff urges that Defendant withheld information during discovery about these topics and cannot now rely on undisclosed evidence at trial. *See id.* Given the complexity of the case and her detailed knowledge of the parties' discovery disputes, the Court appointed Judge Elizabeth D. Laporte (Ret.) as a special master to address Plaintiff's MIL No. 4.¹ *See* Dkt. No. 350.

Judge Laporte served her report and recommendation on March 5, 2021. *See* Dkt. No. 388. Her recommendation is as follows:

¹ Judge Laporte was the discovery Magistrate Judge on the case before she retired from the bench.

- (A) Exclude any testimony by [Defendant's 30(b)(6) witness, in-house attorney Peter Waibel] about the basis for Novartis's willfulness defense, including reliance on the opinion of counsel, e.g., as well reasoned, other than stating without elaboration that when he received notice of this litigation, he looked at the patent in suit, observed the breadth of the claims and set in motion obtaining an opinion of counsel on invalidity;
- (B) Not allow Novartis to introduce any evidence of Mekinist's commercialization not already provided, recognizing, however, that it did provide considerable evidence on this topic in documents and testimony as to its sales and projections done in combination with Tafinlar;
- (C) Plexxikon be permitted to bring to the jury's attention through the [proposed] instruction to the jury by the court during trial when the topic of GSK's lack of knowledge of infringement by its portfolio and (to the extent evidence is permitted to be introduced by Novartis on this issue) the lack of GSK's identification of any freedom-to-operate issues with Tafinlar, as well as oral argument, and if appropriate as the trial proceeds, testimony.

See id. at 7. Defendant filed objections to each of these three recommendations. *See* Dkt. No. 389.

A. Defense to Willful Infringement

Plaintiff first argues that Defendant withheld information relevant to Defendant's contention that it did not willfully infringe the asserted patents. *See* Dkt. No. 264 at 1–5. Plaintiff notes that when asked to identify the factual bases for this contention, Defendant responded that it would rely on the opinion of counsel. *See* Dkt. No. 264-3, Ex. 2 at 14; Dkt. No. 264-5, Ex. 4 at 11. Plaintiff argues that during Mr. Waibel's 30(b)(6) deposition, he obfuscated and did not fully explain Defendant's assertion that it had not willfully infringed the patents-in-suit. *See* Dkt. No. 264 at 2–3. Mr. Waibel acknowledged that he believed that Defendant did not infringe any valid claim of the asserted patents based on the opinion of counsel. *See* Dkt. No. 264-6, Ex. 5 at 24:5–27:3. But he said that the opinion “speaks for itself,” and did not go into further detail *Id.* Plaintiff contends that Defendant should therefore be limited to the opinion of counsel in support of its willfulness defense. *See* Dkt. No. 264 at 2–4.

Defendant urges that Plaintiff was improperly seeking the bases for Defendant's

contentions through a 30(b)(6) witness. *See* Dkt. No. 288 at 1–2. However, as Judge Laporte noted in her report and recommendation, “[w]illfulness in particular includes a subjective component as to the party’s reliance on an attorney opinion and the factual basis for the party’s conduct, which is not the exclusive province of experts.” *See* Dkt. No. 388 at 3. Moreover, as the Federal Circuit has recognized, “[w]illfulness is not an all-or-nothing trait, but one of degree.” *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 811 (Fed. Cir. 2007) (quotation omitted). Yet Mr. Waibel did not substantively respond to Plaintiff’s questions regarding the factual bases for Defendant’s willfulness defense as a 30(b)(6) witness. *See id.* at 2–3. The following exchange is illustrative:

Q. Do you hold the opinion that Novartis does not infringe any valid claim of either of the two Plexxikon patents at issue in this lawsuit?

...

A. Yes.

Q. What is your basis for that opinion?

MR. STEINDLER: Objection. Calls for a legal opinion.

A. As I mentioned, the – the legal opinion – I did not review the legal opinion in preparation for the deposition. The opinion I believe was already produced and it speaks for itself.

See Dkt. No. 389-8, Ex. C-4 at 24:5–22. Although Mr. Waibel answered some questions regarding the timing and process of Defendant’s determination that it did not infringe any valid claims of the asserted patents, *see, e.g., id.* at 34:11–36:1, Defense counsel had earlier stated that they were turning to “the personal deposition of the witness,” *id.* at 29:8–10. As Judge Laporte found, therefore, many of the questions that Mr. Waibel responded to were answered solely in his personal capacity, and not as a corporate representative whose testimony would bind Defendant. *See* Dkt. No. 388 at 2. And significantly, he did not offer any explanation why he—and Defendant—relied on the opinion of counsel.

Having reviewed the parties’ arguments and the deposition in detail, the Court agrees with Judge Laporte’s findings. The Court therefore **GRANTS** Plaintiff’s MIL No. 4 on this basis and will:

Exclude any testimony by Mr. Waibel about the basis for Novartis’s willfulness defense, including reliance on the opinion of counsel, e.g., as well reasoned, other than stating without elaboration that when he received notice of this litigation, he looked at the patent in suit, observed the breadth of the claims and set in motion obtaining an opinion of counsel on invalidity.

See Dkt. No. 388 at 7.

B. Development and Commercialization of Mekinist

Plaintiff next contends that Defendant should be precluded from providing evidence regarding the development and commercialization of Mekinist at trial. *See* Dkt. No. 3–5. As Defendant acknowledges, “Tafinlar and Mekinist are almost exclusively prescribed together for use by patients in *combination*,” and Defendant accordingly “markets the two products in *combination*.” *See* Dkt. No. 389-3, Ex. B at 3 (emphasis in original). Plaintiff requested information regarding Mekinist to challenge Defendant’s theory that Tafinlar’s success was due to its pairing with Mekinist, and not the patented features. *See* Dkt. No. 388 at 3.

As Plaintiff points out, Defendant at least initially refused to designate a witness to testify about Mekinist or produce documents or respond to interrogatories about Mekinist because it was not an accused product. *See, e.g.,* Dkt. No. 264-5, Ex. 4 at 3, 5–6; Dkt. No. 364-8, Ex. 7 at 8–13; Dkt. No. 364-9, Ex. 8 at 7–9. However, Judge Laporte found that Defendant ultimately “provided substantial documents about [Tafinlar and Mekinist’s] combination marketing and sales . . . and considerable testimony regarding the sales in combination.” *See* Dkt. No. 388 at 4; *see also* Dkt. No. 288-3, Ex. B at 9:24-10:7; Dkt. No. 288-4, Ex. C at 17:1–3. She thus concluded that Defendant “appears to have complied with its discovery obligations as to Mekinist’s commercialization.” *Id.* As for information about the development of Mekinist, Defendant notes that it “does not intend to put on evidence regarding its development.” *See* Dkt. No. 288 at 4. Judge Laporte also reasoned that “Plexxikon has failed to show how, if at all, Mekinist’s development pertains to its contribution to the success of its sales in combination with Tafinlar.” *See* Dkt. No. 388 at 4. Rather, “[t]he advantages of the product, rather than how those were achieved, would appear to be what is relevant.” *See id.* Plaintiff did not object, and the Court agrees and adopts Judge Laporte’s reasoning in this regard.

The report and recommendation nevertheless goes on to state that if Defendant “tries to introduce evidence on commercialization and marketing that it withheld, through testimony or documents, it should not be permitted to do so.” *Id.* Judge Laporte therefore recommends that the Court preclude Defendant from introducing “any evidence of Mekinist’s commercialization not already provided” *Id.* at 7. It is this specific recommendation to which Defendant objects. *See* Dkt. No. 389 at 9–10. Defendant argues that because it has fully complied with its discovery obligations, as recognized by Judge Laporte, there is no justification or need to limit Defendant’s presentation of evidence regarding the commercialization of Mekinist. The Court agrees. Of course, neither side may rely on responsive, but unproduced, information at trial. *See* Fed. R. Civ. P. 37(c). But the Court need not predict in advance whether Defendant will attempt to do so. If necessary, Plaintiff may raise objections at trial, and the Court will resolve such issues in context and as they arise. Plaintiff’s MIL No. 4 is therefore **DENIED** without prejudice on this basis.

C. Due Diligence

Lastly, Plaintiff contends that Defendant should be precluded from introducing evidence at trial regarding any due diligence related to Novartis AG’s acquisition of the oncology portfolio from third-party GlaxoSmithKline (“GSK”). *See* Dkt. No. 264 at 3–5. Novartis AG is Defendant’s Swiss parent company. Defendant appears to concede that it intends for Mr. Waibel to testify that GSK did not identify any freedom-to-operate issues associated with Tafinlar as part of Novartis AG’s acquisition of GSK’s oncology portfolio. *See* Dkt. No. 288-3, Ex. B at 4. But as explained below, Plaintiff has had limited access to information about the due diligence associated with the GSK transaction.

Mr. Waibel testified that Defendant was not involved in the GSK acquisition, but rather received a due diligence report for the U.S. products afterward. *See* Dkt. No. 288-2, Ex. A at 43:8–25; 186:12–189:10; 228:23–229:14. Novartis International AG conducted due diligence for the transaction and Novartis AG was the signatory to the agreement (and both are Swiss entities). *Id.* at 188:18–19; 228:23–229:14. Defendant acknowledged that it received a summary of the “freedom to operate” analysis (“FTO summary”) prepared as part of the GSK transaction. *See id.* at 43:8–25; 186:12–189:10; 228:23–229:14. However, Defendant stated that this FTO

summary is privileged, and that it did not have any other responsive, non-privileged documents itself. *See* Dkt. No. 288 at 4; *see also* Dkt. No. 264-10, Ex. 9; Dkt. No. 264-11, Ex. 10. It later produced the publicly available Sale and Purchase Agreement (“SAPA”) for the GSK transaction, which was filed with the United States Securities and Exchange Commission. *See* Dkt. No. 389 at 10–11. The SAPA contains a warranty from GSK that the products in its oncology portfolio—including Tafinlar—did not infringe any intellectual property rights of any third party. *Id.*

Plaintiff made some effort to obtain due diligence information from Novartis AG directly. In December 2018, Judge Laporte—then the discovery Magistrate Judge in this case—granted Plaintiff’s request for a letter to obtain the documents from Novartis AG under the Hague Convention. *See* Dkt. No. 115. Novartis AG opposed the production of these documents, and the Swiss court ultimately denied the request in February 2019. *See* Dkt. No. 264-1 at ¶ 14. Defendant nevertheless offered Mr. Waibel to testify about the due diligence associated with the acquisition of GSK’s oncology portfolio. *See* Dkt. No. 288-2, Ex. A. And although Novartis AG did not produce any documents to *Plaintiff*, it allowed Mr. Waibel to speak with a number of individuals who were involved in the GSK transaction and the due diligence associated with the transaction. *See id.* at 114:15–118:10; 230:2–13. Mr. Waibel then testified during his deposition about what he had learned of the due diligence from these discussions. *Id.* at 39:15–46:17; 126:21–131:12; 141:8–154:14; 186:12–191:24. He said—consistent with the SAPA—that GSK represented that there were no known FTO issues associated with Tafinlar. *Id.* at 129:14–131:12. As Judge Laporte explained in her report and recommendation, however, Plaintiff “was unable to verify or effectively probe this issue for consistency (or lack thereof) with the contemporary documentation.” *See* Dkt. No. 388 at 5.

Judge Laporte did not conclude that Defendant failed to meet its discovery obligations with regard to this information. Nor did she recommend that the Court exclude any evidence on this issue. However, she noted “[t]he unfairness of allowing selective disclosure on this topic” in light of Plaintiff’s limited access to information about the GSK transaction and the related due diligence. *See id.* Rather than recommend exclusion of all evidence regarding the due diligence analysis and GSK’s representation that there was no known infringement by the portfolio it was

selling, Judge Laporte suggested a limiting instruction if the Court allows in such evidence:

In this case, you have heard evidence that GSK made a contractual representation to Novartis's Swiss parent company that certain products transferred as part of Novartis's acquisition of GSK's oncology drug portfolio did not, to GSK's knowledge, infringe or misappropriate any intellectual property rights of any third party [and that GSK told Novartis's Swiss parent that it did not identify and freedom-to-operate issues with Tafenlar during the course of the transaction]. During discovery in this case, Plexxikon sought the due diligence documents underlying that acquisition from Novartis and from Novartis's Swiss parent company, including what information GSK provided as part of the due diligence investigation. Novartis through its counsel represented that it asked its Swiss parent, which is not a party to this case, to provide these documents to Novartis so that they could be produced, and the Swiss parent refused to do so. A Swiss court subsequently denied Plexxikon's formal request to obtain these documents directly from the parent company through the judicial process. It is up to you to decide how much weight, if any, to give these facts in your consideration of the evidence.

Id. at 6–7.

Defendant describes this as an adverse inference instruction, and contends that “it would invite the jury to infer that Novartis and its Swiss parent improperly withheld documents that might be damaging to Novartis's case.” *See* Dkt. No. 389 at 12. Defendant urges that this is unwarranted where Defendant and Novartis AG have acted in accordance with their legal obligations. *See* Dkt. No. 389 at 11–12. Defendant suggests that the jury should therefore have no insight into how the record was developed during discovery. *See id.* at 13.

The Court recognizes the novelty of the circumstances presented here, but disagrees with Defendant's interpretation of the instruction and suggestion to one-sidedly keep the jury in the dark. Both the Federal Rules of Civil Procedure and the Federal Rules of Evidence are intended to ensure the fairness of proceedings. *See, e.g., Shoen v. Shoen*, 5 F.3d 1289, 1292 (9th Cir. 1993) (noting that the Federal Rules of Civil Procedure create a “broad right of discovery” because “wide access to relevant facts serves the integrity and fairness of the judicial process by promoting the search for the truth”); Fed. R. Evid. 102 (“These rules should be construed so as to administer every proceeding fairly . . .”). Allowing Defendant to introduce evidence that it obtained from its Swiss parent company when Plaintiff was unable to probe the veracity or scope of this evidence is unfair. The jury should know about Plaintiff's limitations when weighing this evidence.

Accordingly, the Court **GRANTS** Plaintiff's MIL No. 4 on this basis, and adopts Judge Laporte's recommendation and proposed instruction. If Defendant wants to propose alternative language that will still accomplish the same goal, it may file a proposal for the Court's consideration by June 7, 2021, for discussion during the pretrial conference.

* * *

The Court extends its sincere thanks to Judge Laporte for her thorough work in preparing the report and recommendation. Given the nature of the Court's ruling on this MIL, the Court finds that the parties shall continue to split the fees for Judge Laporte evenly.

II. PLAINTIFF'S MIL NO. 5

Plaintiff also moves to preclude Defendant from offering or soliciting hearsay evidence at trial. *See* Dkt. No. 266. Although Plaintiff does not identify specific testimony, Plaintiff points out that during discovery GSK's corporate witness Dr. Tara Rheault testified to information she learned from talking to another GSK employee about the development of Tafenlar. *See id.* GSK also produced lab notebooks from a senior biologist, Dr. Olivia Rossanese, on the development team. Rather than produce Dr. Rossanese to testify about the work reflected in the notebooks as the author, GSK produced Dr. Rheault as a Rule 30(b)(6) witness. Plaintiff urges that Dr. Rheault, and any other 30(b)(6) witness, may not offer hearsay evidence at trial.


Defendant responds that it does not intend to elicit hearsay testimony from Dr. Rheault or any other witness at trial unless an exception to the hearsay rules applies. *See* Dkt. No. 290 at 2. Rather, Defendant states that it only "expects to call Dr. Rheault at trial to testify about matters within her personal knowledge." *Id.* at 3. Defendant also suggests that Dr. Rheault developed her own personal knowledge about the lab notebooks when preparing for the Rule 30(b)(6) deposition. *See id.* at 3-4.

During a deposition, a Rule 30(b)(6) witness may testify outside his or her *personal* knowledge, and "must testify about information known or reasonably available to the *organization.*" Fed. R. Civ. P. 30(b)(6) (emphasis added). This procedure is intended to "curb the 'bandying' by which officers or managing agents of a corporation are deposed in turn but each disclaims knowledge of facts that are clearly known to persons in the organization and thereby to

1 it.” *See id.*, Notes of Advisory Committee on 1970 Amendments to Rules. The parties do not
2 appear to dispute, however, that at trial, a lay witness “may testify to a matter only if evidence is
3 introduced sufficient to support a finding that the witness has personal knowledge of the matter.”
4 *See* Fed. R. Evid. 602. Accordingly, courts have generally concluded that “a corporate
5 representative may not testify to matters outside his own personal knowledge to the extent that
6 information [is] hearsay not falling within one of the authorized exceptions.” *See Union Pump*
7 *Co. v. Centrifugal Tech. Inc.*, 404 F. App’x 899, 907–08 (5th Cir. 2010); *see also Stryker Corp. v.*
8 *Ridgeway*, No. 1:13-CV-1066, 2016 WL 6585007, at *2–3 (W.D. Mich. Feb. 1, 2016) (collecting
9 cases); *cf. Sara Lee Corp. v. Kraft Foods Inc.*, 276 F.R.D. 500, 502–04 (N.D. Ill. 2011) (admitting
10 30(b)(6) witness deposition testimony regarding corporate policies). But without yet knowing the
11 specific evidence and context in which it will be offered at trial, the Court cannot conclusively rule
12 on issues regarding the foundation for admitting Dr. Rheault’s testimony—or any other witness’s
13 testimony. The Court therefore **DENIES** Plaintiff’s MIL No. 5 without prejudice. The Court will
14 address any objections to Dr. Rheault’s testimony—or any other evidence—at trial as they arise,
15 and in the context of each witness’s proffered testimony and personal knowledge.

16 **IT IS SO ORDERED.**

17 Dated: 6/3/2021

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19 HAYWOOD S. GILLIAM, JR.
20 United States District Judge
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